

Express Mail No.: EV869902616US
Date of Deposit: September 25, 2008

Page 1 of 5
Attorney Docket No.: 25619-501

Please type a plus sign (+) in this box



Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number.

PTO/SB (12-97)

Approved for use through 9/30/00. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Modified Form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)	Application Number 09/806,400
	Filing Date March 30, 2001
	First Named Inventor Shoenfeld
	Group Art Unit 1644
	Examiner Name Ronald B. Schwadron
	Attorney Docket Number 25619-501

U.S. PATENT DOCUMENTS

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A6	3,561,444	09-Feb-1971	Gut Boucher			
	A7	3,699,963	24-Oct-1972	Zaffaroni			
	A8	3,703,173	21-Nov-1972	Dixon			
	A9	3,944,064	16-Mar-1976	Bashaw et al.			
	A10	3,948,262	06-Apr-1976	Zaffaroni			
	A11	3,993,073	23-Nov-1976	Zaffaroni			
	A12	4,624,251	25-Nov-1986	Miller			
	A13	4,635,627	13-Jan-1987	Gam			
	A14	4,690,683	01-Sep-1987	Chien et al.			
	A15	4,837,027	06-Jun-1989	Lee et al.			
	A16	4,917,895	17-Apr-1990	Lee et al.			
	A17	5,110,597	05-May-1992	Wong et al.			
	A18	5,110,738	05-May-1992	Takano et al.			
	A19	5,141,750	25-Aug-1992	Lee et al.			
	A20	5,196,324	23-Mar-1993	Bumol et al.			
	A21	5,284,660	08-Feb-1994	Lee et al.			
	A22	5,344,758	06-Sep-1994	Krillis et al.			
	A23	5,397,771	14-Mar-1995	Bechgaard et al.			
	A24	5,399,347	21-Mar-1995	Trentham et al.			
	A25	5,472,883	05-Dec-1995	Matsuura et al.			
	A26	5,506,110	09-Apr-1996	Matsuura et al.			
	A27	5,643,868	01-Jul-1997	Weiner et al.			
	A28	5,656,272	12-Aug-1997	Le et al.			
	A29	5,681,571	28-Oct-1997	Holmgren et al.			
	A30	5,698,195	16-Dec-1997	Le et al.			
	A31	5,720,955	24-Feb-1998	Weiner et al.			

Express Mail No.: EV869902616US
Date of Deposit: September 25, 2008

Page 2 of 5
Attorney Docket No.: 25619-501

	A32	5,733,542	31-Mar-1998	Haynesworth et al.			
	A33	5,750,309	12-May-1998	Hatakeyama et al.			
	A34	5,763,396	09-Jun-1998	Weiner et al.			
	A35	5,843,445	01-Dec-1998	Weiner et al.			
	A36	5,843,449	01-Dec-1998	Boots et al.			
	A37	5,844,409	01-Dec-1998	Bosselmann et al.			
	A38	5,846,959	08-Dec-1998	Medford et al.			
	A39	5,849,298	15-Dec-1998	Weiner et al.			
	A40	5,856,446	05-Jan-1999	Weiner et al.			
	A41	5,858,364	12-Jan-1999	Weiner et al.			
	A42	5,858,968	12-Jan-1999	Weiner et al.			
	A43	5,858,980	12-Jan-1999	Weiner et al.			
	A44	5,869,093	09-Feb-1999	Weiner et al.			
	A45	5,869,534	09-Feb-1999	Bucala et al.			
	A46	5,874,409	23-Feb-1999	Victoria et al.			
	A47	5,900,247	04-May-1999	Rault et al.			
	A48	5,900,359	04-May-1999	Matsuura et al.			
	A49	5,935,577	10-Aug-1999	Weiner et al.			
	A50	5,945,308	31-Aug-1999	Tang et al.			
	A51	5,961,977	05-Oct-1999	Hafler et al.			
	A52	5,998,223	07-Dec-1999	Matsuura et al.			
	A53	6,019,970	01-Feb-2000	Ghent et al.			
	A54	6,019,975	01-Feb-2000	Bajor et al.			
	A55	6,025,477	15-Feb-2000	Calenoff			
	A56	6,034,102	07-Mar-2000	Aiello			
	A57	6,077,509	20-Jun-2000	Weiner et al.			
	A58	6,114,395	05-Sep-2000	Aiello			
	A59	6,130,059	10-Oct-2000	Covacci et al.			
	A60	6,156,500	05-Dec-2000	Falb			
	A61	6,207,160	27-Mar-2001	Victoria et al.			
	A62	6,224,902	01-May-2001	Alving et al.			
	A63	6,277,969	21-Aug-2001	Le et al.			
	A64	6,309,888	30-Oct-2001	Holvoet et al.			
	A65	6,410,775	25-Jun-2002	Victoria et al.			
	A66	6,610,713	26-Aug-2003	Tracey			
	A67	6,645,504	11-Nov-2003	Weiner et al.			
	A68	6,703,361	09-Mar-2004	Weiner et al.			
	A69	6,783,760	31-Aug-2004	Thorpe et al.			

Express Mail No.: EV869902616US
 Date of Deposit: September 25, 2008

Page 3 of 5
 Attorney Docket No.: 25619-501

	A70	6,790,447	14-Sep-2004	Wildner et al.			
	A71	6,812,205	02-Nov-2004	Weiner et al.			
	A72	6,818,213	16-Nov-2004	Thorpe et al.			
	A73	6,821,964	23-Nov-2004	Colon-Cruz et al.			

U.S. PUBLISHED APPLICATION DOCUMENTS

Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A74	2003/0100036	29-May-2003	Vojdani			
	A75	2003/0114367	19-Jun-2003	Schoenfeld et al.			

FOREIGN PATENT DOCUMENTS

Exam Initials	Cite No.	Foreign Patent Document Office	Foreign Patent Document Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes	Translation No
	B7	EP	EP 0259013	Baker et al.	09-Mar-1988		
	B8	EP	EP 0354742	Faste	14-Feb-1990		
	B9	WO	91/01333	Weiner et al.	07-Feb-1991		
	B10	WO	95/27499	Hafler et al.	19-Oct-1995		
	B11	WO	95/27500	Weiner et al.	19-Oct-1995		
	B12	WO	98/21951	Haas et al.	28-May-1998		
	B13	WO	00/42989	Zarif et al.	27-Jul-2000		
	B14	WO	00/44350	Cevc et al.	03-Aug-2000		
	B15	WO	2006/054281	Harats et al.	26-May-2006		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C41	Altman "Risk Factors in Coronary Atherosclerosis Athero-Inflammation: The Meeting Point", Thrombosis Journal, 1(4): 1-11, 2003.
	C42	Ambrožič et al. "Anti- β 2-Glycoprotein I Antibodies in Children With Atopic Dermatitis", International Immunology, 14(7): 823-830, 2002.
	C43	Bai et al. "Nasal Tolerance Induction as A potential Means of Immunotherapy for Autoimmune Diseases: Implications for Clinical Medicine", Clinical and Experimental Allergy, 30: 1688-1696, 2000.
	C44	Becker et al. "Immunologic Tolerance to Myelin Basic Protein Decreases Stroke Size After Transient Focal Cerebral Ischemia", Proc. Natl. Acad. Sci. USA, 94: 10873-10878, 1997.
	C45	Bili et al. "Anticardiolipin Antibodies and Recurrent Coronary Events: A Prospective Study of 1150 Patients", Circulation, 102: 1258-1263, 2000.
	C46	Birnie et al. "Association Between Antibodies to Heat Shock Protein 65 and Coronary Atherosclerosis. Possible Mechanism of Action of Helicobacter Pylori and Other Bacterial Infections in Increasing Cardiovascular Risk", European Heart Journal, 19: 387-394, 1998.
	C47	Blanas et al. "Induction of Autoimmune Diabetes by Oral Administration of Autoantigen" Science, 274(5293): 1707. Abstract.
	C48	Brey et al. "{Beta}2-Glycoprotein 1-Dependent Anticardiolipin Antibodies and Risk of Ischemic Stroke and Myocardial Infarction: The Honolulu Heart Program", Stroke, 32: 1701-1706, 2001.
	C49	Cabral et al. "The Antiphospholipid/Cofactor Syndromes: A Primary Variant With Antibodies to β 2-Glycoprotein-I But No Antibodies Detectable in Standard Antiphospholipid Assays", American Journal of Medicine, 101: 472-481, 1996.
	C50	Caligiuri et al. "Protective Immunity Against Atherosclerosis Carried by B Cells of Hypercholesterolemic Mice", Journal of Clinical Investigation, 109: 745-753, 2002.
	C51	Chen et al. "Autoimmune-Mediated Vasculopathy", Clinical Immunology, 100(1): 57-70, 2001.
	C52	Chen et al. "Regulatory T Cell Clones Induced by Oral Tolerance: Suppression of Autoimmune Encephalomyelitis", Science, 265(5176): 1237-1240, 1994.
	C53	Chonn et al. " β 2-Glycoprotein I Is A Major Protein Associated With Very Rapidly Cleared Liposomes In Vivo, Suggesting A Significant Role in the Immune Clearance of 'Non-Self' Particles", The Journal of Biological Chemistry, 270(43): 25845-25849, 1995.

C54	Collins et al. "Mucosal Tolerance to A Bacterial Superantigen Indicates A Novel Pathway to Prevent Toxic Shock", <i>Infection and Immunity</i> , 70(5): 2282-2287, 2002.
C55	Davies et al. "Immune Responses to Native β 2-Glycoprotein I in Patients With Systemic Lupus Erythematosus and the Antiphospholipid Syndrome", <i>Rheumatology</i> , 41: 395-400, 2002.
C56	Dotevall et al. "Autoantibodies Against Oxidized Low-Density Lipoprotein and C-Reactive Protein Are Associated With Diabetes and Myocardial Infarction in Women", <i>Clinical Science</i> , 101: 523-531; 2001.
C57	Dunne et al. "Probiotics: From Myth to Reality. Demonstration of Functionality in Animal Models of Disease and in Human Clinical Trials", <i>Antonie van Leeuwenhoek</i> , 76: 279-292, 1999.
C58	Faxon et al. "Atherosclerotic Vascular Disease Conference: Writing Group III: Pathophysiology", <i>Circulation</i> , 109: 2617-2625, 2004.
C59	George et al. "Enhanced Fatty Streak Formation in C57BL/6J Mice by Immunization With Hest Shock Protein-65", <i>Arteriosclerosis, Thrombosis, and Vascular Biology</i> , 19: 505-510, 1999.
C60	George et al. "Hyperimmunization of Apo-E-Deficient Mice With Homologous Malondialdehyde Low-Density Lipoprotein Suppresses Early Atherogenesis", <i>Atherosclerosis</i> , 138: 147-152, 1998.
C61	George et al. "Induction of Early Atherosclerosis in LDL-Receptor-Deficient Mice Immunized With β 2-Glycoprotein I", <i>Circulation</i> , 98: 1108-1115, 1998.
C62	Greaves et al. "Inflammation and Immune Responses in Atherosclerosis", <i>Trends in Immunology</i> , 23(11): 535-541, 2002.
C63	Hajjar et al. "Lipoprotein Trafficking in Vascular Cells", <i>The Journal of Biological Chemistry</i> , 272(37): 22975-22978, 1997.
C64	Hänninen et al. " γ δ T Cells as Mediators of Mucosal Tolerance: The Autoimmune Diabetes Model", <i>Immunological Reviews</i> , 173: 109-119, 2000.
C65	Hoff et al. "Structure of Cholesterol-Containing Particles Accumulating in Atherosclerotic Lesions and Mechanisms of Their Derivation", <i>Current Opinion in Lipidology</i> , 6: 317-325, 1995.
C66	Ilan et al. "Induction of Oral Tolerance in Splenocyte Recipients Toward Pretransplant Antigens Ameliorates Chronic Graft Versus Host Disease in A Murine Model", <i>Blood</i> , 95: 361303619, 2000.
C67	Levine et al. "Antiphospholipid Antibodies and Subsequent Thrombo-Occlusive Events in Patients With Ischemic Stroke", <i>JAMA</i> , 291: 576-584, 2004.
C68	Libby "Inflammation in Atherosclerosis", <i>Nature</i> , 420: 868-874, 2002.
C69	Manzi "Systemic Lupus Erythematosus: A Model for Atherogenesis?", <i>Rheumatology</i> , 39: 353-359, 2000.
C70	Maurer et al. "Developments in Liposomal Drug Delivery Systems", <i>Expert Opinion in Biological Therapy</i> , 1(6): 1-24, 2001.
C71	Mertens et al. "Oxidized LDL and HDL: Antagonists in Atherothrombosis", <i>The FASEB Journal</i> , 15: 2073-2084, 2001.
C72	Pierangeli et al. "A Peptide That Shares Similarity With Bacterial Antigens Reverses Thrombogenic Properties of Antiphospholipid Antibodies In Vivo", <i>Journal of Autoimmunity</i> , 22: 217-225, 2004.
C73	Resch et al. "Competition-Studies With Antioxidized LDL Autoantibodies", 11th International Symposium on Atherosclerosis, Paris, 3.P.138, P.227, 1997. Abstract.
C74	Roselaar et al. "Enhanced Development of Atherosclerosis in Cholesterol-Fed Rabbits by Suppression of Cell-Mediated Immunity", <i>Journal of Clinical Investigation</i> , 96: 1389-1394, 1995.
C75	Ross "The Pathogenesis of Atherosclerosis: A Perspective for the 1990s", <i>Nature</i> , 362: 801-809, 1993.
C76	Rossi et al. "Intravenous or Intranasal Administration of Gliadin Is Able to Down-Regulate the Specific Immune Response in Mice", <i>Scandinavian Journal of Immunology</i> , 50(2): 177-182, 1999.
C77	Roubey "Update on Antiphospholipid Antibodies", <i>Current Opinion in Rheumatology</i> , 12: 374-378, 2000.
C78	Sato et al. "Antiphospholipid Antibody in Localised Scleroderma", <i>Annals of the Rheumatic Diseases</i> , 62: 771-774, 2003.
C79	Schachter "The Pathogenesis of Atherosclerosis", <i>International Journal of Cardiology</i> , 62(Suppl.2): S3-S7, 1997.
C80	Shen et al. "From Interaction of Lipidic Vehicles With Intestinal Epithelial Cell Membranes to the Formation and Secretion of Chylomicrons", <i>Advanced Drug Delivery Reviews</i> , 50: S103-S125, 2001.
C81	Shi et al. "Mechanisms of Nasal Tolerance Induction in Experimental Autoimmune Myasthenia Gravis: Identification of Regulatory Cells", <i>The Journal of Immunology</i> , 162: 5757-5763, 1999.
C82	Stemme et al. "T Lymphocytes From Human Atherosclerotic Plaques Recognize Oxidized Low Density Lipoprotein", <i>Proc. Natl. Acad. Sci. USA</i> , 92: 3893-3897, 1995.
C83	Takeda et al. "Induction of Mucosal Tolerance to E-Selectin Prevents Ischemic and Hemorrhagic Stroke in Spontaneously Hypertensive Genetically Stroke-Prone Rats", <i>Stroke</i> , 33: 2156-2164, 2002.
C84	Thiagarajan et al. " β 2-Glycoprotein I Promotes the Binding of Anionic Phospholipid Vesicles by Macrophages", <i>Arteriosclerosis, Thrombosis, and Vascular Biology</i> , 19: 2807-2811, 1999.
C85	Uyemura et al. "Cross-Regulatory Roles of Interleukin (IL)-12 and IL-10 in Atherosclerosis", <i>Journal of Clinical Investigation</i> , 97(9): 2130-2138, 1996.
C86	Visvanathan et al. "Cellular Immunity to β 2-Glycoprotein-1 in Patients With the Antiphospholipid Syndrome", <i>The Journal of Immunology</i> , 162: 6919-6925, 1999.

Express Mail No.: EV869902616US
Date of Deposit: September 25, 2008

Page 5 of 5
Attorney Docket No.: 25619-501

	C87	Wang et al. "Nasal Administration of Cardiac Myosin Suppresses Autoimmune Myocarditis in Mice", Journal of the American College of Cardiology, 36(6): 1992-1999, 2000.
	C88	Weiner "Oral Tolerance: Immune Mechanisms and the Generation of Th3-Type TGF-Beta-Secreting Regulatory Cells", Microbes and Infection, 3: 947-954, 2001.
	C89	Xu et al. "Association of Serum Antibodies to Heat-Shock Protein 65 With Carotid Atherosclerosis", The Lancet, 341(8840): 255-259, 1993.
	C90	Xu et al. "Association of Serum Antibodies to Heat-Shock Protein 65 With Carotid Atherosclerosis: Clinical Significance Determined in A Follow-Up Study", Circulation, 100: 1169-1174, 1999.

* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ACTIVE 4437096v.1

Express Mail No.: EV869902616US
Date of Deposit: September 25, 2008

Page 1 of 5
Attorney Docket No.: 25619-501

Please type a plus sign (+) in this box

PTO/SB (12-97)

Approved for use through 9/30/00. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

<p>Modified Form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)</p>		Application Number	09/806,400		
		Filing Date	March 30, 2001		
		First Named Inventor	Shoenfeld		
		Group Art Unit	1644		
		Examiner Name	Ronald B. Schwadron		
		Attorney Docket Number	25619-501		
U.S. PATENT DOCUMENTS					
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class
	A6	3,561,444	09-Feb-1971	Gut Boucher	
	A7	3,699,963	24-Oct-1972	Zaffaroni	
	A8	3,703,173	21-Nov-1972	Dixon	
	A9	3,944,064	16-Mar-1976	Bashaw et al.	
	A10	3,948,262	06-Apr-1976	Zaffaroni	
	A11	3,993,073	23-Nov-1976	Zaffaroni	
	A12	4,624,251	25-Nov-1986	Miller	
	A13	4,635,627	13-Jan-1987	Gam	
	A14	4,690,683	01-Sep-1987	Chien et al.	
	A15	4,837,027	06-Jun-1989	Lee et al.	
	A16	4,917,895	17-Apr-1990	Lee et al.	
	A17	5,110,597	05-May-1992	Wong et al.	
	A18	5,110,738	05-May-1992	Takano et al.	
	A19	5,141,750	25-Aug-1992	Lee et al.	
	A20	5,196,324	23-Mar-1993	Bumol et al.	
	A21	5,284,660	08-Feb-1994	Lee et al.	
	A22	5,344,758	06-Sep-1994	Krillis et al.	
	A23	5,397,771	14-Mar-1995	Bechgaard et al.	
	A24	5,399,347	21-Mar-1995	Trentham et al.	
	A25	5,472,883	05-Dec-1995	Matsuura et al.	
	A26	5,506,110	09-Apr-1996	Matsuura et al.	
	A27	5,643,868	01-Jul-1997	Weiner et al.	
	A28	5,656,272	12-Aug-1997	Le et al.	
	A29	5,681,571	28-Oct-1997	Holmgren et al.	
	A30	5,698,195	16-Dec-1997	Le et al.	
	A31	5,720,955	24-Feb-1998	Weiner et al.	

Express Mail No.: EV869902616US
Date of Deposit: September 25, 2008

Page 2 of 5
Attorney Docket No.: 25619-501

	A32	5,733,542	31-Mar-1998	Haynesworth et al.			
	A33	5,750,309	12-May-1998	Hatakeyama et al.			
	A34	5,763,396	09-Jun-1998	Weiner et al.			
	A35	5,843,445	01-Dec-1998	Weiner et al.			
	A36	5,843,449	01-Dec-1998	Boots et al.			
	A37	5,844,409	01-Dec-1998	Bosselmann et al.			
	A38	5,846,959	08-Dec-1998	Medford et al.			
	A39	5,849,298	15-Dec-1998	Weiner et al.			
	A40	5,856,446	05-Jan-1999	Weiner et al.			
	A41	5,858,364	12-Jan-1999	Weiner et al.			
	A42	5,858,968	12-Jan-1999	Weiner et al.			
	A43	5,858,980	12-Jan-1999	Weiner et al.			
	A44	5,869,093	09-Feb-1999	Weiner et al.			
	A45	5,869,534	09-Feb-1999	Bucala et al.			
	A46	5,874,409	23-Feb-1999	Victoria et al.			
	A47	5,900,247	04-May-1999	Rault et al.			
	A48	5,900,359	04-May-1999	Matsuura et al.			
	A49	5,935,577	10-Aug-1999	Weiner et al.			
	A50	5,945,308	31-Aug-1999	Tang et al.			
	A51	5,961,977	05-Oct-1999	Hafler et al.			
	A52	5,998,223	07-Dec-1999	Matsuura et al.			
	A53	6,019,970	01-Feb-2000	Ghent et al.			
	A54	6,019,975	01-Feb-2000	Bajor et al.			
	A55	6,025,477	15-Feb-2000	Calenoff			
	A56	6,034,102	07-Mar-2000	Aiello			
	A57	6,077,509	20-Jun-2000	Weiner et al.			
	A58	6,114,395	05-Sep-2000	Aiello			
	A59	6,130,059	10-Oct-2000	Covacci et al.			
	A60	6,156,500	05-Dec-2000	Falb			
	A61	6,207,160	27-Mar-2001	Victoria et al.			
	A62	6,224,902	01-May-2001	Alving et al.			
	A63	6,277,969	21-Aug-2001	Le et al.			
	A64	6,309,888	30-Oct-2001	Holvoet et al.			
	A65	6,410,775	25-Jun-2002	Victoria et al.			
	A66	6,610,713	26-Aug-2003	Tracey			
	A67	6,645,504	11-Nov-2003	Weiner et al.			
	A68	6,703,361	09-Mar-2004	Weiner et al.			
	A69	6,783,760	31-Aug-2004	Thorpe et al.			

Express Mail No.: EV869902616US
 Date of Deposit: September 25, 2008

Page 3 of 5
 Attorney Docket No.: 25619-501

	A70	6,790,447	14-Sep-2004	Wildner et al.			
	A71	6,812,205	02-Nov-2004	Weiner et al.			
	A72	6,818,213	16-Nov-2004	Thorpe et al.			
	A73	6,821,964	23-Nov-2004	Colon-Cruz et al.			

U.S. PUBLISHED APPLICATION DOCUMENTS

Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A74	2003/0100036	29-May-2003	Vojdani			
	A75	2003/0114367	19-Jun-2003	Schoenfeld et al.			

FOREIGN PATENT DOCUMENTS

Exam Initials	Cite No.	Foreign Patent Document Office	Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes	Translation No
	B7	EP	EP 0259013	Baker et al.	09-Mar-1988		
	B8	EP	EP 0354742	Faste	14-Feb-1990		
	B9	WO	91/01333	Weiner et al.	07-Feb-1991		
	B10	WO	95/27499	Hafler et al.	19-Oct-1995		
	B11	WO	95/27500	Weiner et al.	19-Oct-1995		
	B12	WO	98/21951	Haas et al.	28-May-1998		
	B13	WO	00/42989	Zarif et al.	27-Jul-2000		
	B14	WO	00/44350	Cevc et al.	03-Aug-2000		
	B15	WO	2006/054281	Harats et al.	26-May-2006		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C41	Altman "Risk Factors in Coronary Atherosclerosis Athero-Inflammation: The Meeting Point", Thrombosis Journal, 1(4): 1-11, 2003.
	C42	Ambrožič et al. "Anti- β 2-Glycoprotein I Antibodies in Children With Atopic Dermatitis", International Immunology, 14(7): 823-830, 2002.
	C43	Bai et al. "Nasal Tolerance Induction as A potential Means of Immunotherapy for Autoimmune Diseases: Implications for Clinical Medicine", Clinical and Experimental Allergy, 30: 1688-1696, 2000.
	C44	Becker et al. "Immunologic Tolerance to Myelin Basic Protein Decreases Stroke Size After Transient Focal Cerebral Ischemia", Proc. Natl. Acad. Sci. USA, 94: 10873-10878, 1997.
	C45	Bili et al. "Anticardiolipin Antibodies and Recurrent Coronary Events: A Prospective Study of 1150 Patients", Circulation, 102: 1258-1263, 2000.
	C46	Birnie et al. "Association Between Antibodies to Heat Shock Protein 65 and Coronary Atherosclerosis. Possible Mechanism of Action of Helicobacter Pylori and Other Bacterial Infections in Increasing Cardiovascular Risk", European Heart Journal, 19: 387-394, 1998.
	C47	Blanas et al. "Induction of Autoimmune Diabetes by Oral Administration of Autoantigen" Science, 274(5293): 1707. Abstract.
	C48	Brey et al. "(β 2-Glycoprotein 1-Dependent Anticardiolipin Antibodies and Risk of Ischemic Stroke and Myocardial Infarction: The Honolulu Heart Program", Stroke, 32: 1701-1706, 2001.
	C49	Cabral et al. "The Antiphospholipid/Cofactor Syndromes: A Primary Variant With Antibodies to β 2-Glycoprotein-I But No Antibodies Detectable in Standard Antiphospholipid Assays", American Journal of Medicine, 101: 472-481, 1996.
	C50	Caligiuri et al. "Protective Immunity Against Atherosclerosis Carried by B Cells of Hypercholesterolemic Mice", Journal of Clinical Investigation, 109: 745-753, 2002.
	C51	Chen et al. "Autoimmune-Mediated Vasculopathy", Clinical Immunology, 100(1): 57-70, 2001.
	C52	Chen et al. "Regulatory T Cell Clones Induced by Oral Tolerance: Suppression of Autoimmune Encephalomyelitis", Science, 265(5176): 1237-1240, 1994.
	C53	Chonn et al. " β 2-Glycoprotein I Is A Major Protein Associated With Very Rapidly Cleared Liposomes In Vivo, Suggesting A Significant Role in the Immune Clearance of 'Non-Self' Particles", The Journal of Biological Chemistry, 270(43): 25845-25849, 1995.

C54	Collins et al. "Mucosal Tolerance to A Bacterial Superantigen Indicates A Novel Pathway to Prevent Toxic Shock", <i>Infection and Immunity</i> , 70(5): 2282-2287, 2002.
C55	Davies et al. "Immune Responses to Native β 2-Glycoprotein I in Patients With Systemic Lupus Erythematosus and the Antiphospholipid Syndrome", <i>Rheumatology</i> , 41: 395-400, 2002.
C56	Dotevall et al. "Autoantibodies Against Oxidized Low-Density Lipoprotein and C-Reactive Protein Are Associated With Diabetes and Myocardial Infarction in Women", <i>Clinical Science</i> , 101: 523-531; 2001.
C57	Dunne et al. "Probiotics: From Myth to Reality. Demonstration of Functionality in Animal Models of Disease and in Human Clinical Trials", <i>Antonie van Leeuwenhoek</i> , 76: 279-292, 1999.
C58	Faxon et al. "Atherosclerotic Vascular Disease Conference: Writing Group III: Pathophysiology", <i>Circulation</i> , 109: 2617-2625, 2004.
C59	George et al. "Enhanced Fatty Streak Formation in C57BL/6J Mice by Immunization With Hest Shock Protein-65", <i>Arteriosclerosis, Thrombosis, and Vascular Biology</i> , 19: 505-510, 1999.
C60	George et al. "Hyperimmunization of Apo-E-Deficient Mice With Homologous Malondialdehyde Low-Density Lipoprotein Suppresses Early Atherogenesis", <i>Atherosclerosis</i> , 138: 147-152, 1998.
C61	George et al. "Induction of Early Atherosclerosis in LDL-Receptor-Deficient Mice Immunized With β 2-Glycoprotein I", <i>Circulation</i> , 98: 1108-1115, 1998.
C62	Greaves et al. "Inflammation and Immune Responses in Atherosclerosis", <i>Trends in Immunology</i> , 23(11): 535-541, 2002.
C63	Hajjar et al. "Lipoprotein Trafficking in Vascular Cells", <i>The Journal of Biological Chemistry</i> , 272(37): 22975-22978, 1997.
C64	Hänninen et al. " γ δ T Cells as Mediators of Mucosal Tolerance: The Autoimmune Diabetes Model", <i>Immunological Reviews</i> , 173: 109-119, 2000.
C65	Hoff et al. "Structure of Cholesterol-Containing Particles Accumulating in Atherosclerotic Lesions and Mechanisms of Their Derivation", <i>Current Opinion in Lipidology</i> , 6: 317-325, 1995.
C66	Ilan et al. "Induction of Oral Tolerance in Splenocyte Recipients Toward Pretransplant Antigens Ameliorates Chronic Graft Versus Host Disease in A Murine Model", <i>Blood</i> , 95: 361303619, 2000.
C67	Levine et al. "Antiphospholipid Antibodies and Subsequent Thrombo-Occlusive Events in Patients With Ischemic Stroke", <i>JAMA</i> , 291: 576-584, 2004.
C68	Libby "Inflammation in Atherosclerosis", <i>Nature</i> , 420: 868-874, 2002.
C69	Manzi "Systemic Lupus Erythematosus: A Model for Atherogenesis?", <i>Rheumatology</i> , 39: 353-359, 2000.
C70	Maurer et al. "Developments in Liposomal Drug Delivery Systems", <i>Expert Opinion in Biological Therapy</i> , 1(6): 1-24, 2001.
C71	Mertens et al. "Oxidized LDL and HDL: Antagonists in Atherothrombosis", <i>The FASEB Journal</i> , 15: 2073-2084, 2001.
C72	Pierangeli et al. "A Peptide That Shares Similarity With Bacterial Antigens Reverses Thrombogenic Properties of Antiphospholipid Antibodies In Vivo", <i>Journal of Autoimmunity</i> , 22: 217-225, 2004.
C73	Resch et al. "Competition-Studies With Antioxidized LDL Autoantibodies", 11th International Symposium on Atherosclerosis, Paris, 3.P.138, P.227, 1997. Abstract.
C74	Roselaar et al. "Enhanced Development of Atherosclerosis in Cholesterol-Fed Rabbits by Suppression of Cell-Mediated Immunity", <i>Journal of Clinical Investigation</i> , 96: 1389-1394, 1995.
C75	Ross "The Pathogenesis of Atherosclerosis: A Perspective for the 1990s", <i>Nature</i> , 362: 801-809, 1993.
C76	Rossi et al. "Intravenous or Intranasal Administration of Gliadin Is Able to Down-Regulate the Specific Immune Response in Mice", <i>Scandinavian Journal of Immunology</i> , 50(2): 177-182, 1999.
C77	Roubey "Update on Antiphospholipid Antibodies", <i>Current Opinion in Rheumatology</i> , 12: 374-378, 2000.
C78	Sato et al. "Antiphospholipid Antibody in Localised Scleroderma", <i>Annals of the Rheumatic Diseases</i> , 62: 771-774, 2003.
C79	Schachter "The Pathogenesis of Atherosclerosis", <i>International Journal of Cardiology</i> , 62(Suppl.2): S3-S7, 1997.
C80	Shen et al. "From Interaction of Lipidic Vehicles With Intestinal Epithelial Cell Membranes to the Formation and Secretion of Chylomicrons", <i>Advanced Drug Delivery Reviews</i> , 50: S103-S125, 2001.
C81	Shi et al. "Mechanisms of Nasal Tolerance Induction in Experimental Autoimmune Myasthenia Gravis: Identification of Regulatory Cells", <i>The Journal of Immunology</i> , 162: 5757-5763, 1999.
C82	Stemme et al. "T Lymphocytes From Human Atherosclerotic Plaques Recognize Oxidized Low Density Lipoprotein", <i>Proc. Natl. Acad. Sci. USA</i> , 92: 3893-3897, 1995.
C83	Takeda et al. "Induction of Mucosal Tolerance to E-Selectin Prevents Ischemic and Hemorrhagic Stroke in Spontaneously Hypertensive Genetically Stroke-Prone Rats", <i>Stroke</i> , 33: 2156-2164, 2002.
C84	Thiagarajan et al. " β 2-Glycoprotein I Promotes the Binding of Anionic Phospholipid Vesicles by Macrophages", <i>Arteriosclerosis, Thrombosis, and Vascular Biology</i> , 19: 2807-2811, 1999.
C85	Uyemura et al. "Cross-Regulatory Roles of Interleukin (IL)-12 and IL-10 in Atherosclerosis", <i>Journal of Clinical Investigation</i> , 97(9): 2130-2138, 1996.
C86	Visvanathan et al. "Cellular Immunity to β 2-Glycoprotein-1 in Patients With the Antiphospholipid Syndrome", <i>The Journal of Immunology</i> , 162: 6919-6925, 1999.

Express Mail No.: EV869902616US
Date of Deposit: September 25, 2008

Page 5 of 5
Attorney Docket No.: 25619-501

	C87	Wang et al. "Nasal Administration of Cardiac Myosin Suppresses Autoimmune Myocarditis in Mice", Journal of the American College of Cardiology, 36(6): 1992-1999, 2000.
	C88	Weiner "Oral Tolerance: Immune Mechanisms and the Generation of Th3-Type TGF-Beta-Secreting Regulatory Cells", Microbes and Infection, 3: 947-954, 2001.
	C89	Xu et al. "Association of Serum Antibodies to Heat-Shock Protein 65 With Carotid Atherosclerosis", The Lancet, 341(8840): 255-259, 1993.
	C90	Xu et al. "Association of Serum Antibodies to Heat-Shock Protein 65 With Carotid Atherosclerosis: Clinical Significance Determined in A Follow-Up Study", Circulation, 100: 1169-1174, 1999.

* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ACTIVE 4437096v.1